EXHIBIT 7

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ORIGINAL ARTICLE

Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications

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Abstract

Objective. The aim of this study was to determine the surgical success and complication rates of mixed type of mesh materials compared with Prolene mesh in sling surgery over a 4-year follow-up period. *Material and methods.* Between 2005 and 2007, broad-based double-forced sling operations were performed in 144 women with stress incontinence using three different types of mesh material. Group I consisted of 48 patients in whom Vypro® mesh (Ethicon, USA) was used; group II of 48 patients in whom Ultrapro® mesh (Ethicon) and group III of 48 patients in whom Prolene® light mesh (Ethicon) was used. The patients' data and the success of the operation were evaluated based on the 24 h pad test, International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) scoring and Korman questionnaire analysis. *Results.* The ICIQ-SF score, the number of pads used and the results of 24 h pad test were statistically lower in group II at postoperative month 48 ($p < 0.05$). The rate of postoperative complications was lower in Group II than in the other groups ($p < 0.05$). The continence rates of groups I, II and III were 84.7%, 91.6% and 85.1%, respectively, in the 48th postoperative month. *Conclusions.* Ultrapro mesh can be used in sling surgery owing to its higher success rates, and lower vaginal and urethral extrusion and de novo urgency rates, which have also been shown in clinical studies.

Key Words: *incontinence, mixed mesh, sling surgery, synthetic mesh, Ultrapro® mesh*

Introduction

There are several advantages to using synthetic slings, including a reduction in the morbidity of harvesting from a second surgical site, shortened operative time, early postoperative patient recovery and an unlimited supply of artificial material, which have led to an increase in the number of sling procedures [1–3].

Recognized complications of the synthetic sling procedure include urinary storage and voiding symptoms, such as de novo urgency, urge incontinence, incomplete bladder emptying and urinary retention, or urethral, bladder and vaginal extrusion [4]. It is important for the surgeon to be familiar with the characteristics of each type of mesh material, as their qualities tend to determine the biocompatibility [5–7]. Macropore monofilament polypropylene mesh material has the best track record of host tissue integration, incorporation, safety and biocompatibility compared with polytetrafluoroethylene, polyester or silicone [3,8].

The literature reveals few experimental studies on mixed mesh materials such as Vypro® mesh (semiabsorbable multifilament; non-absorbable polypropylene plus absorbable polyglactin) and Ultrapro® mesh (semiabsorbable monofilament; non-absorbable polypropylene plus absorbable poliglecaprone) [5,9]. In animal studies, it has been shown that the tensile force increases with time and tissue integration occurs more frequently with Ultrapro mesh [5]. No clinical studies exist in the literature on the use of semiabsorbable mixed meshes in sling surgery. Therefore, the aim of this randomized prospective clinical study was to determine the clinical results, surgical success and

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complication rates of mixed type mesh materials compared with Prolene® mesh in sling surgery over a 4-year follow-up period. This study is also valuable because it is the first randomized prospective clinical study to evaluate the use of mixed semiabsorbable synthetic mesh materials in sling surgery.

Material and methods

Study population

In this randomized prospective study, broad-based double-forced sling (DFS) operations were performed in 144 incontinent patients using three different types of mesh material between 2005 and 2007. Three patients were lost during the study period. The flowchart is presented in Figure 1. In total, 141 patients had complete follow-up evaluation. The same surgical technique was performed in each patient by one surgeon and the mesh types were randomly selected. The patients were followed up by three other surgeons who joined the study and who did not know which mesh group the patients belonged to. The results of 4-year follow-up were recorded.

The 144 patients and use of mesh materials were randomly allocated into three different groups: group I (n = 48), Vypro mesh; group II (n = 48), Ultrapro mesh; and group III (n = 48), Prolene light mesh (cpp: condensed monofilament non-absorbable polypropylene). Patients with failed previous anti-incontinence surgery, clinical and/or urodynamic diagnoses of stress-type urinary incontinence, positive stress test and previous hysterectomy history were included in the study. Patients with urodynamically mixed type urinary incontinence and detrusor overactivity, 100 ml or greater postvoid residual, contraindication to anaesthesia, pelvic organ prolapse, pregnancy, neurogenic bladder, bladder outlet obstructions, urinary fistula, or active urinary or vaginal infection were excluded from the study.

Detailed history, pelvic examination, urine culture, Q-tip and Boney test, supine stress test, 24 h pad test [10], cystoscopy and urodynamic measurements of patients were recorded. All of the patients had stress incontinence. The patients filled out

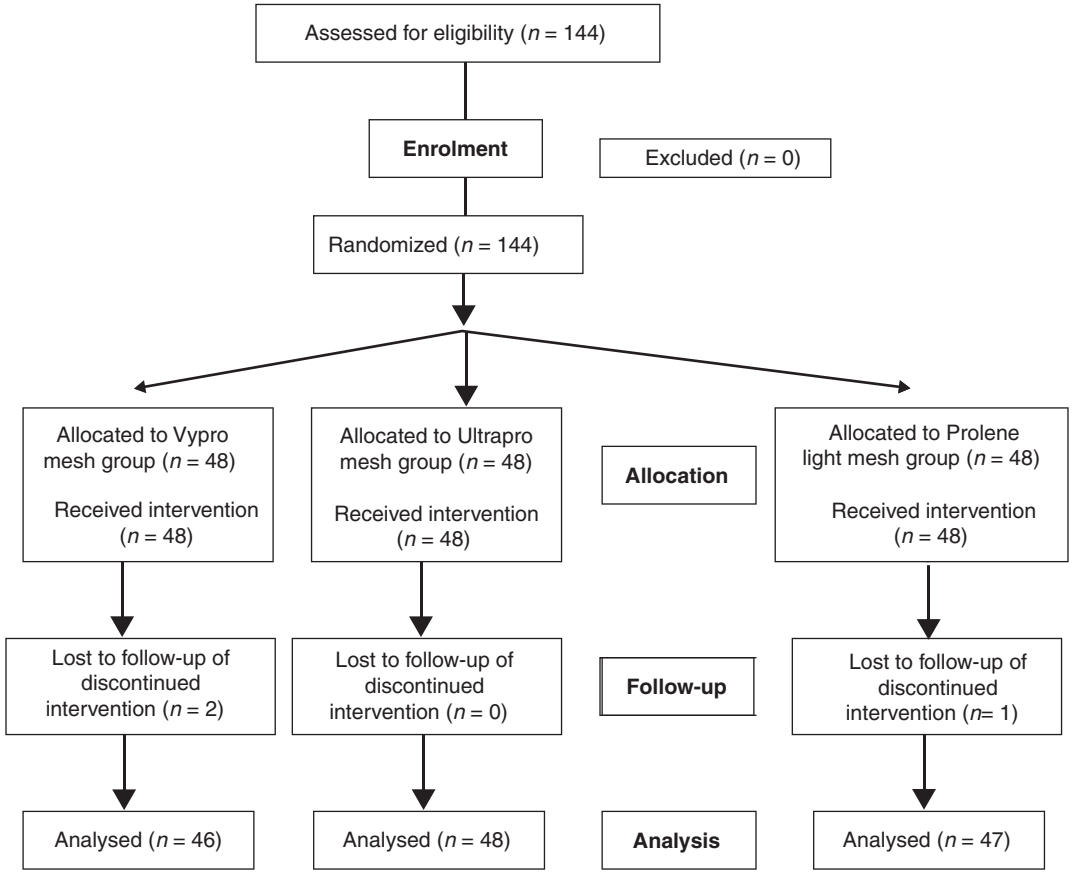

Figure 1. Consort diagram illustrating the randomized study design.

the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and Korman questionnaire [11,12] for quality of life and urinary incontinence. A validated Turkish version of the ICIQ-SF questionnaire [13] was used.

Outcome assessment

Urethral mobility was evaluated with the Q-tip test and a lateral cystogram. If the urethral angle was higher than 35°, it was defined as hypermobility. In the 24 h pad test, no need for pad use or pad weight of less than 2 g was considered cured; pad weight of 2–8 g was considered mild; pad weight of 9–19 g was considered moderate; and pad weight of 20 g or over was considered severe [10]. Considering the pad counts, no use of pads was considered cured. The Korman questionnaire form is shown in Appendix 1. In the Korman questionnaire analysis, storage and voiding symptoms and patient satisfaction were asked about. Storage symptoms (questions 6–8) and voiding symptoms (questions 2–5) were scored. Patient satisfaction was assessed with questions 14 and 15. Each question about voiding and storage symptoms was scored between 0 and 2, and the total scores were evaluated as follows: mild (0–2), moderate (3–5) and severe (6–8). Patients having no, mild and moderate/severe symptoms were considered cured, improved and failed, respectively [11,12].

Quality of life and incontinence were evaluated based on ICIQ-SF scores related to incontinence. The ICIQ-SF question form, consisting of six questions on quality of life and incontinence, was used to determine the patients' ICIQ-SF scores. This scoring was done according to questions 3, 4 and 5. The patients were first evaluated in the second postoperative month. This evaluation was based on continence status, vaginal examination and any findings of infection or extrusion. All these evaluations were repeated in the sixth, 12th, 24th and 48th postoperative months. The patients' results and success of the operation were assessed according to ICIQ-SF scores, pad test and Korman questionnaire analysis.

The primary outcome measure was urinary continence rates 4 years after synthetic sling surgery. Secondary outcome measures were complications after synthetic sling surgery for stress urinary incontinence: urethral and vaginal extrusion, de novo urgency, urinary retention and suture granuloma rates 4 years after synthetic sling surgery.

Randomization

The patients and the mesh materials were randomized 1:1:1 to each group in blocks of three via a centralized computerized system to ensure a good balance of participant characteristics in each group.

Sample size

Power analysis with the PASS program showed that the beta of the study was 0.15 based on the pad test and Korman questionnaire parameters, and the power of study was 90%. The beta of the study was 0.08 based on ICIQ-SF score and the power of study was 92%. At 92% power, with 2.3 standard deviation, for 0.95 reliability, the sample size was determined to be 48 patients in each group.

Operative technique

The patients were operated on in the lithotomic position under regional or general anaesthesia after vaginal douching and sterile draping. The labia majora were temporarily fixed on the inner hip. The vaginal introitus was retracted with a weighted speculum. A urethral 20 F Foley catheter was inserted and the balloon was blown up to 20 ml. An incision with an inverted "A" shape was made on the anterior wall of the vagina. The upper part of the A-shaped incision was formed into an island belonging to the vaginal wall. This patch was 3 × 4 cm in most of the patients. The size of the mesh was individualized during the procedure. The proximal anterior vaginal wall (the lower part of the "A") was dissected as a flap (Figure 2a). Synthetic mesh materials were first sutured onto the upper part of the A on the vaginal island with absorbable Vicryl® sutures. Then, with two polypropylene sutures, these meshes were fixed on both the right and left sides of the island in a helical manner to form a suspension, and using curved Kishner needles, the prolene sutures were transferred to the suprapubic area. Thus, the meshes were fixed with two polypropylene sutures, and the sutures moved to the suprapubic area using Kishner needles at the same point where they were tied down. These sutures were ligated on the fascia of the rectus muscle in a crosswise manner (Figure 2b). The mobile lower wing was advanced onto the island and sutured onto the vaginal skin with intermittent sutures using 3-0 Monocryl sutures (Figure 2c). Cystourethroscopy was performed to achieve control of the bladder and urethra after passage of the needle. After confirmation that the bladder and urethra were normal, the prolene sutures were ligated crosswise in the suprapubic region. Special attention was paid not to create much tension on the mesh material. Urethral catheters were removed on the postoperative second day, followed by suprapubic ultrasound to measure the amount of posturination residue.

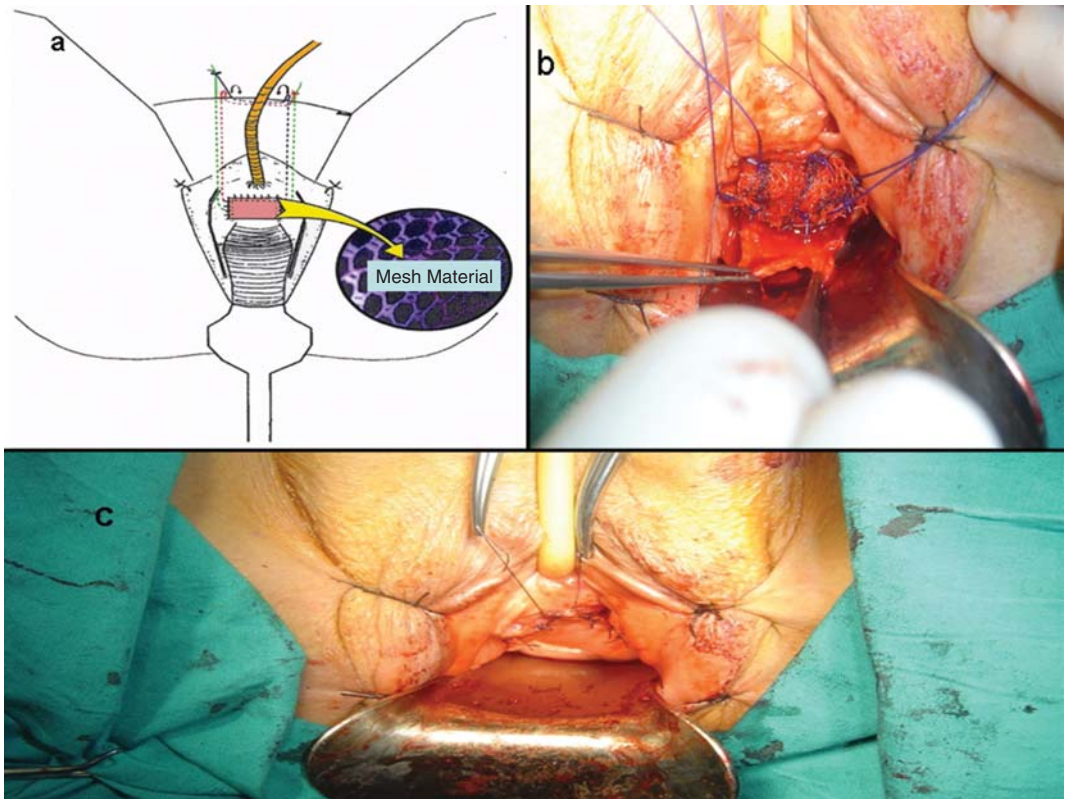

Figure 2. (a) "A"-shaped incision on the anterior vaginal wall. The upper part of A was used for the vaginal sling through minimal dissection. (b) Division of the vaginal wing, fixation of the mesh onto the vaginal island, and vaginal flap. (c) Suturing the vaginal flap (lower A) onto the vaginal mucosa to cover the island patch that holds the mesh inside.

Statistical analysis

The data were analysed with SPSS version 13.5 (SPSS, Chicago, IL, USA). Continuous data were expressed as mean ± standard deviation (SD). Analysis of variance (ANOVA), paired sample *t* test and Kruskal–Wallis H test were used to determine statistical significance. Categorical data were expressed as value and percentage. Values of $p < 0.05$ were considered statistically significant.

The study was approved by the Ataturk Training and Research Hospital regional Ethics Committee of Ankara, Turkey, on 10 September 2005. All the patients signed an informed consent form. All the terminology conformed to the standards recommended by the ICS/IUGA [14].

Results

The mean operation time was 55 min (32–80 min). The hospitalization time was 2 days. The demographic characteristics of the patients in groups I, II and III are presented in Table I. Patients underwent a urodynamic test before the operation, and the results of this test were similar among the groups. Intraoperatively, none of the patients developed bowel, bladder and/or urethral perforations, or any complications.

The mean ICIQ-SF scores, 24 h pad test scores and pad counts of the patients, preoperatively and 6, 12 and 48 months postoperatively, are shown in Table II. In all groups, the postoperative ICIQ-SF scores, pad counts and pad test results were lower 48 months after the operation than in preoperative evaluations ($p < 0.05$) (Table II).

The ICIQ-SF score, number of pads used and weight of pads in the 24 h pad test were lower, and improvement was detected in voiding and storage symptoms in group II 48 months postoperatively ($p < 0.05$). The results obtained in the 48th postoperative month showed that the continence rates and patient satisfaction were higher in group II ($p < 0.05$) (Table III).

The rates of voiding and storage symptoms, continence and patient satisfaction based on Korman analysis are shown in Table III. In the 48th postoperative month, 39 patients (84.7%) in group I, 44 (91.6%) in group II and 40 (85.1%) in group III had continence, and the patient satisfaction rates were 37 (80.4%) in group I, 41 (85.4%) in group II and 38 (80.5%) in group III (Table III).

Table I. Demographic characteristics of the patients.

	Group I	Group II	p^a	Group III	p^b	p^c
Age (years)	50.06 ± 9.2 (36–75)	50.9 ± 8.8 (34–72)	0.92	48.1 ± 7.9 (31–64)	0.82	0.67
Parity	2.4 ± 0.9 (1–5)	3.1 ± 1.6 (1–7)	0.57	3.1 ± 1.09 (1–5)	0.58	0.89
BMI (kg/m^2)	27.8 ± 3.4 (21–35)	27.9 ± 4.1 (21–40)	0.96	27.7 ± 2.9 (23–33)	0.94	0.96
Diabetes mellitus	5 (10.4)	3 (6.25)	0.67	5 (10.4)	0.92	0.56
Hypertension	11 (22.9)	7 (14.5)	0.56	8 (16.6)	0.63	0.83
Menopause	10 (20.8)	11 (22.9)	0.89	8 (16.6)	0.69	0.54
Anticholinergic use	8 (16.6)	8 (16.6)	0.98	10 (20.8)	0.86	0.86
Previous history of incontinence surgery	4 (8.33)	5 (10.4)	0.78	4 (8.33)	0.92	0.73
Previous hysterectomy	4 (8.33)	4 (8.33)	0.86	2 (4.16)	0.48	0.51

Data are shown as mean ± SD (minimum–maximum) or number of observations (%).
BMI = body mass index.
ANOVA was used in all comparisons ($p < 0.05$). [a] Group I vs group II; [b] group I vs group III; [c] group II vs groups I and III.

Postoperative complications are shown in Table IV. Postoperatively, five patients (10.86%) in group I, two (4.16%) in group II and four (8.51%) in group III developed de novo urgency symptoms. The urine retention in six patients resolved in a mean of 10.6 days. Two patients (4.34%) in group I, one (2.08%) in group II and two (4.25%) in group III had vaginal extrusion. Urethral extrusion has been observed in one patient in each of groups I and III. All patients with vaginal and urethral extrusions were those who had previously undergone failed incontinence surgery. In the 48th postoperative month, four patients (8.69%) in group I, one (2.08%) in group II, and four (8.51%) in group III had incontinence. The postoperative complication rates were lower in group II ($p < 0.05$) (Table IV).

Discussion

Various materials have been used in pubovaginal sling operations for the treatment of stress incontinence, but no consensus has been formed on the ideal prosthetic material. When considering the principles of infection prevention and host tissue integration, it seems clear that theoretically one would favour implantation of a type I synthetic mesh. At present, the mesh material most commonly used in sling surgery is monofilament macroporous polypropylene [3].

Table II. Comparison of the preoperative and postoperative ICIQ-SF scores, 24 h pad test and pad counts.

	Preop	Postop. month 6	Postop. month 12	Postop. month 48	p^a
Group I					
Mean total ICIQ-SF score	19.3 ± 1.2	3.1 ± 0.9	2 ± 0.7	2.1 ± 0.5	0.012
24 h pad test (g)	27.2 ± 9.1	4.2 ± 6.4	2.1 ± 1.4	2.3 ± 1.1	0.016
No pad use (cure)	–	40 (86.9)	41 (89.1)	39(84.7)	–
Mean total pad count	6.1 ± 1.04	0.93 ± 0.5	0.62 ± 0.4	0.65 ± 0.3	0.023
Group II					
Mean total ICIQ-SF score	20.1 ± 0.4	2.1 ± 0.8	1.2 ± 0.6	0.8 ± 0.5	0.0076
24 h pad test (g)	28.7 ± 9.3	2.7 ± 6.2	2 ± 1.1	1.3 ± 0.8	0.0069
No pad use (cure)	–	44 (91.6)	45 (93.7)	44 (91.6)	–
Mean total pad count	6.8 ± 1.4	0.83 ± 0.5	0.33 ± 0.2	0.2 ± 0.15	0.018
Group III					
Mean total ICIQ-SF score	18.8 ± 1.4	2.7 ± 0.8	1.7 ± 0.4	1.5 ± 0.3	0.016
24 h pad test (g)	32.4 ±10.2	3.03 ± 5.8	2.4 ± 3.8	2.4 ± 1.1	0.012
No pad use (cure)	–	41 (87.2)	41 (87.2)	40 (85.1)	–
Mean total pad count	7.1 ± 1.8	1.1 ± 0.8	0.94 ± 0.6	0.83 ± 0.54	0.014

Data are shown as mean ± SD or number of observations (%).
ICIQ-SF = International Consultation on Incontinence Questionnaire – Short Form; perop. = preoperative; postop. = postoperative.
Paired sample t test was used in all comparisons ($p < 0.05$). [a] All groups, preoperative vs postoperative 48th month.

Table III. Comparison of the postoperative ICIQ-SF scores, pad counts, 24 h pad test and Korman questionnaire analysis results in the 48th month.

	Group I	Group II	p^a	Group III	p^b	p^c
Mean total ICIQ-SF score	2.1 ± 0.5	0.8 ± 0.5	0.0072	1.5 ± 0.3	0.32	0.012
No pad use (cure)	39 (84.7)	44 (91.6)	0.032	40 (85.1)	0.23	0.034
Mean total pad count	0.65 ± 0.3	0.2 ± 0.15	0.014	0.83 ± 0.54	0.76	0.0086
Mean total 24 h pad test (g)	2.3 ± 1.1	1.3 ± 0.8	0.0189	2.4 ± 1.1	0.89	0.011
No voiding and storage symptoms	37 (80.4)	44 (91.6)	0.023	40 (85.1)	0.56	0.032
Urinary continence rate	39 (84.7)	44(91.6)	0.025	40 (85.1)	0.85	0.038
Patient satisfaction rate	37 (80.4)	41 (85.4)	0.021	38(80.5)	0.91	0.033

Data are shown as mean ± SD or number of observations (%).
ICIQ-SF = International Consultation on Incontinence Questionnaire – Short Form.
ANOVA was used in all comparisons ($p < 0.05$). [a] Group I vs group II; [b] group I vs group III; [c] group II vs groups I and III.

The literature presents several clinical studies on the use of synthetic materials in incontinence surgery; however, there are no studies on the use of mixed type of mesh materials. The authors believe that the present study may be valuable because it is the first randomized prospective clinical study to evaluate the use of mixed synthetic mesh materials in sling surgery.

There has been a limited number of animal and in vitro studies on the use of semiabsorbable mixed type mesh materials. In an experimental study planned by this clinic, Mersilene, polypropylene, Vypro and Ultrapro mesh materials were used. That study showed time-dependent changes in the biomechanical properties of these materials (Ultrapro and Vypro) relative to the classical meshes (Prolene and Mersilene). Ultrapro and Vypro meshes were shown to have more intense incorporation with the main tissue. This finding was attributed to macropores and the semiabsorbable quality of these meshes. This was explained by tissue compatibility resulting from monofilament semiabsorbable quality of the mesh [5].

The continence rates, ICIQ-SF scores and 24 h pad test results of the Ultrapro mesh synthetic sling group were better in the 48th postoperative month. The success rates of the other groups were lower.

The published incidence rate of urinary retention after single incision sling surgery for incontinence has been reported to be 3.2% [15]. In another study, the incidence of urethral obstruction after synthetic sling surgery was reported to be 20% [16]. In the present study, the urinary retention rate in the Ultrapro mesh group was 4.16%, but none of the patients suffered permanent retention.

The rate of de novo urgency after synthetic sling surgery ranges from 5% to 25% [17]. In the present study, this rate was 7.8%, while it was 4.16% in the Ultrapro mesh group. The rate of de novo urgency in group II was lower than in the other groups.

Most of the extrusion of graft materials may occur relatively late, usually 1–4 years postoperatively. In a study by Amundsen et al., urethral extrusion developed in 9 months (range 3–18 months) [18]. In the present study, it developed in a mean of 12.3 months, which is similar to the literature.

The incidence of extrusion has been reported to be from 0.3% to 23%. Higher rates have been reported when synthetic sling materials were used [19]. Several factors, including specific properties of the sling material, local ischaemia, poor mesh incorporation and basic tissue compatibility, have contributed to the wide range of extrusion rates [4]. In another study,

Table IV. Postoperative complications.

	Group I	Group II	p^a	Group III	p	p^c
Vaginal erosion	2 (4.34)	1 (2.08)	0.023	2 (4.25)	0.83	0.024
Urethral erosion	1 (2.17)	–	0.032	1 (2.12)	0.82	0.03
Suture granuloma	3 (6.52)	1 (2.08)	0.027	3 (6.38)	0.87	0.024
Urine retention	2 (4.34)	2 (4.16)	0.075	2 (4.25)	0.85	0.08
Incontinence	4 (8.69)	1 (2.08)	0.019	4 (8.51)	0.89	0.018
De novo urgency	5 (10.86)	2 (4.16)	0.016	4 (8.51)	0.42	0.028

Data are shown as number of observations (%).
Kruskal–Wallis H test was used in all comparisons ($p < 0.05$). [a] Group I vs group II; [b] group I vs group III; [c] group II vs groups I and III. The rate of postoperative complications in group II was statistically significantly lower than in the other groups.

which used synthetic materials, these rates were between 0% and 12% [20]. In the only randomized controlled equivalence trial comparing extrusions rates between tension-free vaginal tape (TVT) and a suprapubic urethral support sling (SPARC), Lord et al. [21] reported rates of 4.8% and 10.5%, respectively. In the present study, the vaginal extrusion rate was lower in the Ultrapro mesh group (2.08%).

The exact aetiology of urethral extrusion is unknown [22]. The American Urological Association clinical guidelines panel performed a meta-analysis of the literature on anti-incontinence procedures, and identified urethral extrusion in 27 out of 1515 patients (2.7%) after synthetic sling placement [23]. In the present study, urethral extrusion was not determined in the Ultrapro mesh group.

In this study, the vaginal and urethral extrusion and de novo urgency rates were lower, and the continence rates were higher in group II compared with the other groups. The Ultrapro mesh prevents local infections because of the reduced amount of polypropylene, larger pores and poliglecaprone content. In addition to these characteristics, loosely woven mesh provides large areas where the tissue can grow inwards. This inward growth may enable union of the transplanted tissue with the surrounding tissue, allowing it to be fixed at its location. Poliglecaprone affords optimal tissue unification and reaction. In this study, the low complication rates in the Ultrapro mesh group are largely related to the absorbability of poliglecaprone, which fixes the tissue onto the tissue and prevents the mesh shift and rubbing. The rate of erosive complications, in particular, was lower in the Ultrapro mesh group. In the DFS technique [24], this can be attributed to vaginal wall blockade and the vaginal island located between the mesh and urethra, which leads to less pressure and a lower risk of ischaemia, extrusion and infection. The literature presents only one clinical study on the use of a broad-based sling. Polypropylene mesh and bone fixation were used, yielding a success rate of 82% [25]. In the present study, the mesh fixated on the rectus fascia rather than the pubic bone. This technique seems to yield higher success rates and lower complication rates than those with the techniques described in the literature. Moreover, as a synthetic material, Ultrapro mesh shows the best analogy with type I macropore monofilament, because its absorbable poliglecaprone part is a monofilament.

In conclusion, in the treatment of stress incontinence, as well as the surgical technique, the characteristics of the synthetic mesh materials, their shape and application method affect the success of surgery. This surgical method also needs evaluation, especially in comparison with the traditional TVT sling procedure. The incidence of urethral and vaginal extrusions following Ultrapro mesh synthetic sling procedures appears to be lower than that with other synthetic slings in a 4-year follow-up. Ultrapro mesh, with its high success rates, and low vaginal and urethral extrusion and de novo urgency rates determined in clinical studies, can be reliably and effectively used in sling surgery. Further clinical and experimental studies are needed to determine the ideal mesh material.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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Appendix 1. Korman questionnaire form [11,12]

1. Compared to before surgery, how is your urinary stream? (Better, Same, Worse)
2. Do you have to strain to urinate? (Always, Sometimes, Never)
3. Do you feel that you empty your bladder completely? (Always, Sometimes, Never)
4. Do you have dribbling after you void? (Always, Sometimes, Never)
5. Do you use a catheter in order to empty your bladder? (Yes, No, Sometimes)
6. When you get the urge to urinate, can you make it to the bathroom without wetting? (Always, Sometimes, Never)
7. During the daytime, how often do you urinate? (__ to __ hours between voids)
8. How often do you urinate at night? (__ to __ hours between voids)
9. Do you leak with any of the following manoeuvres? (Cough, Strain, Sneeze, Run, Jog, Walk, Change position, Lying flat, Simply standing, Always)
10. Do you have to wear pads to stay dry? (__ to __ minipads a day, __ to __ maxipads a day, __ to __ diapers a day)
11. Do you have to change panties during the day? (__ to __ times a day)
12. Do you have problems with pelvic pain? (Yes, No, Sometimes)
13. If you are having intercourse, is it painful? (Yes, No, Sometimes)
14. Knowing what you know now, would you still have chosen to have surgery for this condition? (Yes, No, Maybe)
15. All things considered, how is your urine control compared to what it was before the operation? (Better, Same, Worse)
16. What medications are you currently taking?
17. What other surgeries have you had since the bladder surgery?